

AMENDMENT TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A solid oral controlled release pharmaceutical composition for administration to a subject in need thereof comprising: (a) a therapeutically effective amount of a pharmaceutically active ingredient; and (b) a controlled release modifying complex wherein said complex comprises: (i) a primary release modifying agent; (ii) a secondary release modifying agent; and (iii) an auxiliary release modifying agent wherein said primary, secondary and auxiliary release modifying agents are present in amounts that synergistically extend the release of the pharmaceutically active ingredient, and further wherein component (a) is admixed with components (i), (ii) and (iii) of component (b).

2. (Cancelled)

3. (Currently Amended) A solid oral controlled release pharmaceutical composition for administration to a subject in need thereof comprising: (a) a therapeutically effective amount of a pharmaceutically active ingredient; and (b) a controlled release modifying complex wherein said complex comprises: (i) a primary release modifying agent selected from low molecular weight hydrophilic polymers; (ii) a secondary release modifying agent selected from high molecular weight hydrophilic polymers; and (iii) an auxiliary release modifying agent selected from the starch derivatives wherein said primary, secondary and auxiliary release modifying agents are

present in amounts that synergistically extend the release of the pharmaceutically active ingredient, and further wherein component (a) is admixed with components (i), (ii) and (iii) of component (b).

4. (Currently Amended) A solid oral controlled release pharmaceutical composition for administration to a subject in need thereof comprising: (a) a therapeutically effective amount of a pharmaceutically active ingredient; and (b) a controlled release modifying complex wherein said complex comprises: (i) a primary release modifying agent selected from low molecular weight hydrophilic polymers; or (ii) a secondary release modifying agent selected from high molecular weight hydrophilic polymers; and (iii) an auxiliary release modifying agent selected from the starch derivatives wherein said primary, secondary and auxiliary release modifying agents are present in amounts that synergistically extend the release of the pharmaceutically active ingredient, and further wherein component (a) is admixed with components (i), (ii) and (iii) of component (b).

5. (Original) The pharmaceutical composition of claim 1 wherein the dosage form is a tablet, caplet or capsule.

6. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a macrolide or azide antibiotic or a derivative thereof.

7. (Original) The pharmaceutical composition of claim 6, wherein the macrolide is an erythromycin derivative or its pharmaceutically acceptable hydrates, salts or esters.

8. (Cancelled)

9. (Original) The pharmaceutical composition of claim 7, wherein the erythromycin derivative is selected from the group consisting of clarithromycin, josamycin, midecamycin, kitamycin, roxithromycin, rokitamycin, oleandomycin, miocamycin, flurithromycin, and rosaramicin, and their pharmaceutically acceptable hydrates, salts and esters.

10-21. (Cancelled)

22. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a low soluble high dose API or a derivative thereof.

23. (Presently Presented) The pharmaceutical composition of claim 22, wherein the low soluble high dose API or a derivative is selected from the group consisting of acetazolamide, allopurinol, atenolol, carbamazepine, cefadroxil, cephalexin, chloramphenicol, cefuroxime axetil, chlorthalidone, cilastazol, cimetidine, clarithromycin, clofazemine, dapsone, diclofenac sodium, diiodohydroxy quinolone, diloxamide furoate, disulfiram, erythromycin, erythromycin estolate, erythromycin stearate, ethacrynic acid, ethionamide, ethopropazine hydrochloride, ferrous fumarate, fluconazole, flurbiprofen, furazolidone, griseofulvin, hydrochlorthiazide, ibuprofen,

itraconazole, ketoconazole, ketoprofen, labetalol hydrochloride, levodopa, linezolid, lithium carbonate, magaldrate, mebendazole, mefenamic acid, megestrol acetate, mercaptopurine, mesalamine, nalidixic acid, nateglinide, niclosamide, nitrofurantoin, norfloxacin, oxcarbazepine, oxyphenbutazone, paracetamol, phenindione, phenobarbitone, phenylbutazone, phenylsulphathiazole, piperazine phosphate, proguanil hydrochloride, promethazine theoclate, propylthiouracil, quinidine sulphate, quinine sulphate, quinidochlor, rifampicin, simvastatin, spironolactone, succinylsulphathiazole, sulphadiazine, sulphadimethoxine, sulphadimidine, sulphafurazole, sulphaphenazole, thiabendazole, timidazole, tolbutamide, triamterene, sulphamethoxazole and their pharmaceutically acceptable salts, ester and hydrates.

24. (Original) The pharmaceutical composition of claim 23, wherein the active ingredient is Clarithromycin.

25-28. (Cancelled)

29. (Original) The pharmaceutical composition of claim 1, wherein the primary release modifying agent is a low molecular weight polyethylene oxide.

30. (Previously Presented) The pharmaceutical composition of claim 1, wherein the primary release modifying agent comprises a low molecular weight polyethylene oxide that has a molecular weight of at least about 100,000.

31. (Previously Presented) The pharmaceutical composition of claim 1, wherein the primary release modifying agent comprises a low molecular weight polyethylene oxide that has a molecular weight ranging from 100,000 to 900,000.

32. (Original) The pharmaceutical composition of claim 1, wherein the secondary release modifying agent is a high molecular weight polyethylene oxide.

33. (Previously Presented) The pharmaceutical composition of claim 1, wherein the secondary release modifying agent comprises a high molecular weight polyethylene oxide that has a molecular weight of at least about 1,000,000.

34. (Previously Presented) The pharmaceutical composition of claim 1, wherein the secondary release modifying agent comprises a high molecular weight polyethylene oxide that has a molecular weight ranging from 1,000,000 to 9,000,000.

35. (Original) The pharmaceutical composition of claim 1, wherein the auxiliary release modifying agent is a starch derivative selected from pregelatinized starch, partially pregelatinized starch, retrograded starch, or a combination thereof.

36. (Original) The pharmaceutical composition of claim 1, wherein the auxiliary release modifying agent is a retrograded starch.

37. (Original) The pharmaceutical composition of claim 1, wherein said composition further comprises at least one pharmaceutically acceptable additive selected from diluents, fillers, binders, glidants, and lubricants.

38. (Original) The pharmaceutical composition of claim 1, wherein said composition further comprises an optional coating which is designed for the modification of drug release.

39. (Presently Presented) The pharmaceutical composition of claim 38, wherein the coating composition is selected from the group consisting of cellulose ethers such as ethyl cellulose, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, and others such as polyvinyl alcohol, polyvinyl pyrrolidone, methacrylic acid derivatives, resins, clays, long chain hydrocarbons, long chain carboxylic acids, long chain carboxylic acid esters, long chain alcohols and mixtures thereof.

40. (Original) The pharmaceutical composition of claim 1, wherein said composition further comprises an optional coating which is not designed for the modification of drug release.

41. (Presently Presented) The pharmaceutical composition of claim 40, wherein the coating composition is selected from the group consisting of cellulose ethers, polyvinyl alcohol, polyvinyl pyrrolidone, methacrylic acid derivatives, resins, clays, long chain hydrocarbons, long chain carboxylic acids, long chain carboxylic acid esters, long chain alcohols and mixtures thereof.

42. (Original) The pharmaceutical composition of claim 1, wherein said composition comprises from about 0.1 percent weight to about 90 percent weight of the active pharmaceutical ingredient.

43. (Original) The pharmaceutical composition of claim 42, wherein said composition comprises from about 0.1 percent weight to about 80 percent weight of the active pharmaceutical ingredient.

44. (Original) The pharmaceutical composition of claim 1, wherein the composition comprises from about 1 percent weight to about 90 percent weight of the release modifying complex.

45. (Original) The pharmaceutical composition of claim 44, wherein the composition comprises from about 5 percent weight to about 85 percent weight of the release modifying complex.

46. (Original) The pharmaceutical composition of claim 45, wherein the composition comprises from about 10 percent weight to about 80 percent weight of the release modifying complex.

47. (Original) The pharmaceutical composition of claim 1, wherein the primary release modifying agent comprises from about 1 percent weight to about 90 percent weight of the release modifying complex.

48. (Original) The pharmaceutical composition of claim 47, wherein the primary release modifying agent comprises from about 5 percent weight to about 80 percent weight of the release modifying complex.

49. (Original) The pharmaceutical composition of claim 48, wherein the primary release modifying agent comprises from about 5 percent weight to about 70 percent weight of the release modifying complex.

50. (Original) The pharmaceutical composition of claim 1, wherein the secondary release modifying agent comprises from about 1 percent weight to about 95 percent weight of the release modifying complex.

51. (Original) The pharmaceutical composition of claim 50, wherein the secondary release modifying agent comprises from about 5 percent weight to about 90 percent weight of the release modifying complex.

52. (Original) The pharmaceutical composition of claim 1, wherein the auxiliary release modifying agent comprises from about 1 percent weight to about 95 percent weight of the release modifying complex.

53. (Original) The pharmaceutical composition of claim 52, wherein the auxiliary release modifying agent comprises from about 5 percent weight to about 95 percent weight of the release modifying complex.

54. (Original) The pharmaceutical composition of claim 53, wherein the auxiliary release modifying agent comprises from about 10 percent weight to about 95 percent weight of the release modifying complex.

55-145. (Cancelled)